REMARKS/ARGUMENTS

Claims 19 through 31 are currently pending.

No new subject matter has been added.

Rejection of Claims 19, 23 through 25 and 27 through 31 under 35 U.S.C. § 103(a)

Claims 19, 23 through 25 and 27 through 31 were rejected under 35 U.S.C. § 103(a) as being unpatentable over US Patent No. 6,485,760, issued to Matsuyama (hereinafter "Matsuyama") in view of U.S. Patent No. 5,431,916, issued to White (hereinafter "White") and US Patent No. 6,303,586, issued to Mcpeak (hereinafter "Mcpeak").

Applicants respectfully traverse this rejection for at least the following reasons.

The present invention pertains to soft gel capsules that are prepared by a unique process. The process by which the soft gel capsule is prepared includes the steps of heating rice bran oil to about 35° C in a container, adding a filler, adding corosolic acid, stirring the mixture, and encapsulating the mixture in the soft gel capsule. The result is a soft gel capsule that encapsulates a liquid containing corosolic acid.

Matsuyama, the primary reference, discloses an oral composition, a hard "tablet" (See column 5, line 50 through column 6, line 20) with a "powered herbal extract containing corosolic acid". As the Office Actions of September 9, 2003, April 7, 2004 and November 16, 2004 note, Matsuyama fails to teach or suggest in any of its disclosure that anything but a tablet that contains a "powdered herbal extract containing Corosolic acid".

As noted above, the present invention is drawn to a soft gel capsule that encapsulates a liquid that contains corosolic acid. Matsuyama is devoid of any teaching for such an encapsulated liquid composition.

Furthermore, Matsuyama fails to provide any motivation or an expectation of success such that one having ordinary skill in the art to formulate a soft gel capsule that encapsulates a liquid that contains corosolic acid.

Additionally, Matsuyama fails to teach or suggest or provide any motivation or an expectation of success to one having ordinary skill in the art to formulate a soft gel capsule that

encapsulates a liquid that contains corosolic acid by a process that includes heating rice bran oil, adding filler, adding corosolic acid and then encapsulating the mixture in the soft gel capsule.

Further, Matsuyama fails to teach or suggest, provide any motivation or an expectation of success to a person having ordinary skill in the art to heat rice bran oil to about 35° C in a container, add a filler, add corosolic acid, stir the mixture, and encapsulate the mixture in the soft gel capsule.

White, a secondary reference, fails to remedy the deficiencies of Matsuyama.

White generically discloses the use of soft gelatin capsules with pharmaceuticals.

White serves to teach a "genus"; that is that materials can be formulated within a soft gelatin capsule. However, White does not provide any teaching or suggestion, an expectation of success or any motivation to select corosolic acid and an oil carrier. The present invention should be viewed as a "species" selection; that is the selection of specific components (corosolic acid and an oil carrier) that are placed within a soft gelatin capsule. Species type claims are patentable over a genus; a species anticipates a genus, but a genus does not anticipate nor make obvious a species.

Moreover, the preparation of soft gelatin capsules containing ingredients is not always straightforward. Applicants and their company, often spend years developing formulations that are efficacious, that can be encapsulated by a soft gelatin capsule, selecting the appropriate carrier which is often problematic, and or that do not degrade the soft gelatin capsule or crystallize from the carrier. Selection of an inappropriate carrier may well not dissolve the active agent, i.e., corosolic acid, may degrade the active agent, and or be detrimental to the soft gelatin capsule that encapsulates the formulation.

White fails to teach or suggest, provide any motivation or an expectation of success to a person having ordinary skill in the art to heat rice bran oil to about 35° C in a container, add a filler, add corosolic acid, stir the mixture, and encapsulate the mixture in the soft gel capsule.

Consequently, neither reference, alone or in combination, teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art that unitary soft gel capsule that encapsulates liquified corosolic acid suitable for oral administration could be

prepared by heating rice bran oil, adding a filler, adding the herb, i.e., corosolic acid, and encapsulating the mixture into a soft gel capsule.

Mcpeak does not remedy the deficiencies of any of the aforementioned references, alone or in combination.

Mcpeak discloses various rice bran derivatives.

However, Mcpeak fails to teach or suggest, provide any motivation of an expectation of success to one of ordinary skill in the art that a rice bran derivative, liquid or solid, could be included in any type of tablet, pill, capsule, etc., let alone a soft gel capsule.

Mcpeak fails to teach or suggest, provide any motivation or an expectation of success to one of ordinary skill in the art that a rice bran derivative of any type could be used to solubilize an herb, such as corosolic acid.

Mcpeak fails to teach or suggest, provide any motivation or an expectation of success to one of ordinary skill in the art that a fluid composition of an oil carrier, i.e., rice bran oil, and an herb, i.e., corosolic acid, could be encapsulated in a unitary soft gel capsule that can be administered orally.

Mcpeak is devoid of any teachings of any herbs, any capsule type delivery systems, and encapsulation of any material.

Mcpeak fails to teach or suggest, provide any motivation or an expectation of success to a person having ordinary skill in the art to heat rice bran oil to about 35° C in a container, add a filler, add corosolic acid, stir the mixture, and encapsulate the mixture in the soft gel capsule.

Consequently, none of the references, alone or in combination, teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art that unitary soft gel capsule that encapsulates liquified corosolic acid suitable for oral administration could be prepared by heating rice bran oil, adding a filler, adding the herb, i.e., corosolic acid, and encapsulating the mixture into a soft gel capsule.

Reconsideration and withdrawal of the rejection is respectfully requested.

Rejection of Claims 20 through 22 under 35 U.S.C. § 103(a)

Claims 20 through 22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Matsuyama, in view of White and Mcpeak as applied to claims 19, 23 through 25 and 27 through 31 above and further in view of U.S. Patent No. 3,683,088, issued to Walter (hereinafter "Walter"), U.S. Patent No. 3,665,009, issued to Dickinson (hereinafter Dickinson), and US Patent No. 6,407,068, issued to LaGrone (hereinafter "LaGrone").

Applicants respectfully traverse this rejection for at least the following reasons.

The arguments presented above with regard to Matsuyama, White and Mcpeak are reiterated here in their entirety for all purposes.

Walter does not remedy the deficiencies of any of the aforementioned references, alone or in combination.

Walter discloses the use of bee's wax as an additive in combination with 1,3,3a,4,9,9a-hexahydro-2-(3,3-dimethyl-allyl)-4,9-ethano-2H- benz[f]isoindol-10-one, soybean oil, soy lecithin, hydrogenated soybean oil, yellow beeswax and partially hydrogenated mixed vegetable oils.

Walter fails to teach or suggest anything regarding corosolic acid. Walter specifically identifies 1,3,3a,4,9,9a-hexahydro-2-(3,3-dimethyl-allyl)-4,9-ethano-2H- benz[f]isoindol-10-one as the active ingredient. These two materials are unrelated.

Walter fails to teach or suggest, provide any motivation or an expectation of success to a person having ordinary skill in the art that a unitary soft gel capsule that encapsulates liquified corosolic acid suitable for oral administration could be prepared by heating rice bran oil, adding a filler, adding the herb, i.e., corosolic acid, and encapsulating the mixture into a soft gel capsule.

None of the references, alone or in combination, teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art that unitary soft gel capsule that encapsulates liquified corosolic acid suitable for oral administration could be prepared by

heating rice bran oil, adding a filler such as bees wax, adding the herb, i.e., corosolic acid, and encapsulating the mixture into a soft gel capsule.

Dickinson does not remedy the deficiencies of any of the aforementioned references, alone or in combination.

Dickinson discloses that soft gel capsules can be prepared for oral administration by filling with a suspension of a 1-carbamoylpyrazole-4-sulfonamide, soybean oil, hydrogenated soybean oil, beeswax, vegetable shortening and of soy lecithin. The carbamoylpyrazole compounds of Dickinson are used as antiinflammatories.

First, Dickinson discloses a suspension. This helps to further support that a person having ordinary skill in the art would need to experiment to find a suitable combination of materials to provide a soft gelatin fill composition that is dissolved.

Furthermore, Dickinson fails to teach or suggest anything regarding corosolic acid. Dickinson specifically identifies 1-carbamoylpyrazole-4-sulfonamides as the active ingredient. These two materials are unrelated.

Dickinson fails to teach or suggest, provide any motivation or an expectation of success to a person having ordinary skill in the art that a unitary soft gel capsule that encapsulates liquified corosolic acid suitable for oral administration could be prepared by heating rice bran oil, adding a filler, adding the herb, i.e., corosolic acid, and encapsulating the mixture into a soft gel capsule.

None of the references, alone or in combination, teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art that unitary soft gel capsule that encapsulates liquified corosolic acid suitable for oral administration could be prepared by heating rice bran oil, adding a filler, adding the herb, i.e., corosolic acid, and encapsulating the mixture into a soft gel capsule.

LaGrone does not remedy the deficiencies of any of the aforementioned references, alone or in combination.

LaGrone teaches the use of silica to prevent diabetes.

LaGrone fails to mention anything regarding corosolic acid.

LaGrone fails to mention anything regarding a soft gelatin capsule.

LaGrone fails to teach or suggest, provide any motivation or an expectation of success to a person having ordinary skill in the art that a unitary soft gel capsule that encapsulates liquified corosolic acid suitable for oral administration could be prepared by heating rice bran oil, adding a filler (such as silica), adding the herb, i.e., corosolic acid, and encapsulating the mixture into a soft gel capsule.

None of the references, alone or in combination, teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art to that a unitary soft gel capsule that encapsulates liquified corosolic acid suitable for oral administration could be prepared by heating rice bran oil, adding a filler (silica), adding the herb, i.e., corosolic acid, and encapsulating the mixture into a soft gel capsule.

Reconsideration and withdrawal of the rejection is respectfully requested.

Rejection of Claim 26 under 35 U.S.C. § 103(a)

Claim 26 was were rejected under 35 U.S.C. § 103(a) as being unpatentable over Matsuyama, in view of White, Mcpeak, Walter, Dickinson, and LaGrone, as applied to claims 19 through 25 in further in view of U.S. Patent No. 5,980,902, issued to Shanmugasundaram (hereinafter "Shanmugasundaram").

Applicants respectfully traverse this rejection for at least the following reasons.

The arguments presented above with regard to all references are reiterated here in their entirety for all purposes.

Shanmugasundaram does not remedy the deficiencies of any of the aforementioned references, alone or in combination.

Shanmugasundaram discloses the extract of *Gymnema sylvestre* for controlling blood sugar.

Shanmugasundaram fails to mention anything regarding a soft gelatin capsule.

Shanmugasundaram fails to identify any oil type carriers.

Shanmugasundaram fails to mention corosolic acid.

Shanmugasundaram fails to teach or suggest, provide any motivation or an expectation of success such that a person having ordinary skill in the art that a unitary soft gel capsule that encapsulates liquified corosolic acid suitable for oral administration could be prepared by heating rice bran oil, adding a filler, adding the herb, i.e., corosolic acid and *Gymnema sylvestre*, and encapsulating the mixture into a unitary soft gel capsule.

Reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

This application now stands in allowable form and reconsideration and allowance is respectfully requested. If a telephonic consultation would help to expedite the processing of the application, the Examiner is urged to contact the attorney below at the Examiner's convenience.

No fee is deemed necessary. The Commissioner is hereby authorized to charge any deficiencies or credit any overpayments to Deposit Account No. 04-1420.

Respectfully submitted,

DORSEY & WHITNEY LLP
Customer Number 25763

Date: September 15, 2006

By: _____
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